

REMARKS

Applicants submit this amendment in response to an Office Action mailed by the USPTO on May 17, 2005.

In this amendment, applicants have canceled claims 21-29, and added new claims 30-38. Upon entry of this amendment, claims 1-29 will be canceled and claims 30-38 will be pending in the present application.

In the Office Action, the Examiner rejected claims 21, 22 and 23 under 35 U.S.C. §102(b) as being anticipated by Pirtle, Jr. (U.S. Patent No. 3,628,523). Although the Examiner's rejection is moot in view of applicants' cancellation claims 21-29, applicants respectfully submit that claims 30-38 are patentable over the prior art of record in this application, as discussed in more detail below.

Pirtle, Jr. is directed to a syringe for the injection of radioactive medicinal and diagnostic compositions into the body. The syringe includes a cylindrical body 10 formed of lead glass, with a hypodermic needle 13 being attached thereto. A stainless steel plunger 15 is slidably disposed within the cylindrical body 10. As indicated at column 1, lines 63-65, the stainless steel plunger is "adapted for slidable engagement with the inner wall of said cylindrical body [by being] coated with a soft resilient material selected from the group consisting of resilient polymeric materials, rubber and combinations of these." See, also column 3, lines 13-16. Lubrication between the inner wall of the cylindrical body 10 and the plunger 15 is achieved by providing the resilient material 20 on the plunger 15, not on the inner surface of the body. Pirtle, Jr. neither teaches nor suggests depositing lubricant on the inner wall of the cylindrical body. In

fact, Pirtle, Jr. clearly teaches away from such a method of lubricating a syringe body by disclosing that the lubricant, i.e., the soft resilient material, is deposited only on the steel plunger.

In contrast, applicants' invention, as recited by claims 30-38, is directed to a method of lubricating an inner surface of a medical container having a stopper, the method comprising the step of "depositing a lubricant on the inner surface over a limited area of the inner surface, the limited area having an axial length greater than an axial length of the stopper, and the lubricant not contacting the plunger," and to a medical container made in accordance with that method. Thus, applicants' invention deposits a lubricant on the inner surface of the container. Pirtle, Jr., on the other hand, expressly teaches away from such an invention by disclosing that the lubricant be deposited on the plunger, not on the inner surface of the tubular body. Pirtle, Jr. neither teaches nor suggests providing a lubricant anywhere other than on the plunger. Applicants respectfully submit that such a disclosure teaches away from a lubricant deposited on an inner surface of a tubular barrel, as recited by applicants' claims. Clearly, the only teaching provided by Pirtle, Jr. with respect to the lubrication of the plunger is to provide the lubricant on the plunger.

Applicants respectfully submit that Pirtle, Jr. fails to teach or suggest each and every element set forth in the claims of the present application. Thus, Pirtle, Jr. cannot stand as a proper 35 U.S.C. §102(b) reference. Applicants respectfully submit that claims 30-38 are patentable over the prior art references cited in the present application, including Pirtle, Jr.

The Examiner also rejected claims 24-29 under 35 U.S.C. §103(a) as being unpatentable over Pirtle, Jr. in view of Funderburk (U.S. Patent No. 5,456,940), Richard et al. (U.S. Patent No.

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4,252,118), Akhavi (U.S. Patent No. 4,266,559), and Tischlinger (U.S. Patent No. 3,889,351). Again, while the Examiner's rejection is moot in view of applicants' cancellation claims 21-29, applicants respectfully submit that claims 30-38 are patentable over the prior art of record in this application, as discussed in more detail below.

The Examiner has acknowledged that Pirtle, Jr. fails to disclose "the conventionality of (1) plastic syringes, (2) glass syringes, (3) and the use of silicone to provide a coating to the inner wall of the syringe." The Examiner has relied upon the various secondary references in an attempt to overcome the deficiencies in the disclosure of Pirtle, Jr. However, in view of the failure of Pirtle, Jr. to teach or suggest every element recited by claim 30, as set forth in detail above, applicants respectfully submit that their invention is not rendered obvious by the Examiner's proposed combination of Pirtle, Jr. and any of Funderburk, Richard et al., Akhavi, and Tischlinger, because none of those references overcome the deficiency identified above with regard to Pirtle, Jr. In fact, when discussing Funderburk, which is the reference relied upon by the Examiner as disclosing a system for lubricating a syringe barrel, the Examiner has correctly pointed out that Funderburk "does not teach that the lubricant should be limited to selected portions of the syringe." To address that deficiency in the disclosure of Funderburk, the Examiner looks to Pirtle, Jr. However, applicants respectfully maintain that the Examiner's reliance on Pirtle, Jr. to disclose lubricating a portion of the syringe barrel is no longer tenable. As noted above, Pirtle, Jr. only discloses providing a coating of soft resilient material on the plunger to "maintain the plunger 15 in slidable engagement with the inner wall of the cylindrical body 10." Pirtle, Jr. neither teaches nor suggests providing a lubricant anywhere other than on

the plunger. Applicants respectfully submit that such a disclosure teaches away from a lubricant deposited on an inner surface of a container and over a limited area of the inner surface, where the limited area has an axial length greater than an axial length of a stopper used with the container and where the lubricant does not contact a plunger used with the container, as recited by applicants' claims.

In addition, applicants respectfully submit that a person of ordinary skill in the art would not be motivated to modify Pirtle, Jr. based upon the separate or collective disclosure of the other cited references, or based upon the knowledge of a person skilled in the art to achieve applicants' invention. The syringe and plunger disclosed by Pirtle, Jr. are constructed of materials that substantially alleviate the passage of gamma rays emitted by most commonly employed medical and diagnostic radioisotopes (e.g., a cylindrical body made of lead glass having a density of approximately 2 to about 6.5 (see, e.g., column 2, lines 19-23) and a stainless steel plunger). There is neither teaching nor suggestion in Pirtle, Jr. of making the cylindrical body or plunger from any other materials. Using the materials disclosed by Pirtle, Jr., applicants respectfully submit that the lubricant must be deposited on the plunger rod as a soft resilient polymeric and/or rubber material. Depositing a silicone lubricant, as claimed by applicants, to all or part of the inner surface of the cylindrical body of Pirtle, Jr. would not provide the necessary lubrication between the glass body and stainless steel plunger rod.

Plunger rods for more general use syringes (e.g., for injection or withdrawal of a liquid substance into or from a body) are typically made of plastic. The substitution of a plastic plunger rod for the stainless steel plunger rod of Pirtle, Jr. would not provide the shielding against gamma

ray exposure required in the device of Pirtle, Jr. That hypothetical substitution would render the Pirtle, Jr. device inoperable and is thus impermissible. See, e.g., MPEP §2143.01 "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious." Citations omitted.

Applicants further respectfully submit that, even if a person skilled in the art would be motivated to modify any of the cited references to incorporate the teaching of Pirtle, Jr. (which applicants do not concede is the case), the result would not render the claims of the present application obvious. The resultant teaching of such a hypothetical combination would be a plastic plunger rod having a soft resilient polymeric material and/or rubber as a lubricant provided on the plunger rod. Applicants respectfully submit that such a teaching is not what is claimed in the present application.

Applicants' position with regard to the proposed hypothetical combination of the cited references with each other, or with the knowledge of a person skilled in the art may be summarized as follows:

1. Pirtle, Jr. cannot be modified to incorporate the teachings of any of the cited references because such a combination would render the device of Pirtle, Jr. inoperable, which is not permitted (see, e.g., MPEP §2143.01); and
2. The modification of any other cited reference to incorporate the teaching of Pirtle, Jr. would result in a device having a plastic plunger rod with a soft resilient polymeric material and/or rubber as a lubricant provided on the plunger rod.

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In view of the forgoing remarks, and the remarks set forth above with regard to claims 30-38 and Pirtle, Jr., applicants respectfully submit that the claims pending in the present application are unpatentable over Pirtle, Jr. in view of Funderburk, Richard et al., Akhavi, and Tischlinger, and any other prior art of record in the present application.

Applicants respectfully submit that this amendment is fully responsive to the Office Action, and that claims 30-38 are patentable over the prior art of record in the present application, and are thus in condition for allowance. Applicants thus respectfully request early and favorable reconsideration of the present application.


While no fees are believed due in connection with this amendment (other than the RCE and Petition fees, which are approved via papers filed concurrently herewith), applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this amendment, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: September 28, 2005

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